DETAILED ACTION

Status of the Application

Receipt of the Request for Continued Examination (RCE) under 37 C.F.R. 1.114, the Amendment to Claims and Applicant's Arguments/Remarks, all filed 04/14/2011 is acknowledged.

Applicant has overcome the following rejection(s) by virtue of the amendment to the Claims and/or persuasive remarks:

(1) The 35 U.S.C. 103(a) rejection of Claims 1-3, 8, 10 and 12 over Skinner (U.S. 6,210,710) has been withdrawn;

(2) The 35 U.S.C. 103(a) rejection of Claims 1-3, 8, 10 and 12 over Baichwal (U.S. 5,958,456) in view of Skinner (U.S. 6,210,710) has been withdrawn;

(3) The 35 U.S.C. 103(a) rejection of Claims 1, 3, 5, 8, 10 and 12 over Illum (U.S. 5,935,604) has been withdrawn.

Claims 1-20 are pending in this action. Claims 1, 3-5 and 11 have been amended. New claims 13-20 were added. Claims 2, 9 and 11 have previously been withdrawn. Claims 1, 3-8, 10 and 12-20 are currently under consideration. Claims 1, 3-8, 10 and 12-20 are rejected.

Information Disclosure Statement

No Information Disclosure Statement is associated with this application.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 04/14/2011 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3-5, 7-8, 10 and 12-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Skinner, U.S. 6,210,710 (hereinafter referred to as Skinner) and Wong et. al., U.S. 6,548,083 (hereinafter referred to as Wong).

Skinner teaches sustained release pharmaceutical compositions that can be formulated in controlled-release dosage form suitable for oral administration (Abstract; Col. 6, Lns. 14-18). According to Skinner said compositions may comprise gellan gum (Col. 3, Ln.7); one or more hydrophilic polymers selected from the group consisting of guar gum (Col. 3, Lns. 5-6), hydroxypropylmethylcellulose (Abstract; Col. 1, Ln.58-Col. 2, Ln.5; Col. 13, Lns. 29-50; Col. 14, Lns. 47-51, 54-58), carboxymethyl cellulose sodium salt (Col. 2, Ln. 65) and xanthan gum (Col. 3, Ln. 6); that can be used alone or

as mixtures thereof (Col. 2, Ln. 64-Col. 3, Ln. 24 as applied to Claims 1 and 3-4). The compositions also comprise at least one drug (Col. 3, Lns. 25-30) and one or more non-active pharmaceutically acceptable additives such as metal ions, colorants, taste maskers, dietary components, excipients, binding agents, coatings, preservatives and mixtures thereof (Col. 4, Lns. 46-65 as applied to Claims 8 and 12). The dosage forms are made in forms of a solid matrix such as tablets, lozenges, gelcaps, suspensions, gels and the like (Col. 5, Lns. 10-27; Col. 14, Lns. 25-30 as applied to as applied to Claims 1 and 10).

Skinner emphasizes that said polymer blends contain at least two components, while even three, four or five can be used (Col. 2, Lns. 29-37). Skinner teaches that blending of HPMC with other polysaccharides such as guar gum and/or carboxymethylcellulose is a common blending approach as seen in the prior art (Col. 1, Lns. 30-45; see also US4,389,393; US 4,756,911; US 5,451,409 US 4,704,285; US 4,259,314) and discloses specific combinations comprising hydroxypropylmethylcellulose (HPMC), guar gum and/or carboxymethylcellulose (Col. 13, Lns. 29-50; Col. 14, Lns. 47-51, 54-58 as applied to Claims 13-17). Skinner discloses the combination of hydrophilic polymers that allow control the release rate of the dosage form (Col. 2, Lns. 8-23).

Skinner teaches the drug is selected from the group consisting of anti-inflammatory drugs, hypnotic sedatives, antipyretic analgesics, stimulants, drugs for the central nervous system, drugs for the peripheral nervous system, opthalmics, vasoconstrictors, vasodilators, circulatory drugs, drugs for respiratory organs, digestive drugs, hormonal agents, vitamins, antidiabetics, antitumor agents,

antibiotics, and chemotherapeutic agents (Col. 3, Ln. 31-Col. 4, Ln. 33; Col. 13, Ln.57-Col. 14, Ln.7 as applied to Claim 5). Though Skinner is silent regarding specific drugs in Claim 7, the generic classes disclosed by Skinner read on such species-specific drugs as clarithromycin and ciprofloxacin as antibiotics; orlistat as anti-obesity drug; and azidotimidine as anti-HIV drug (Col. 3, Ln. 31-Col. 4, Ln. 33 as applied to Claim 7).

Skinner does not disclose wherein gellan gum constitutes from about 20 to about 50 wt % of the matrix (Claim 1). Skinner is silent regarding the drug has preferred absorption in the stomach (Claim 6). Skinner does not teach upon wetting the dosage form, a gel is produced for more than 5 hours (Claim 18); more than 24 hours (Claim 19); or more than 1 week in gastric fluid simulation (Claim 20).

Wong teaches an active agent dosage form which is adapted for retention in the stomach and useful for the prolonged delivery of an active agent formulation to a fluid environment of use (Abstract). Wong also teaches said dosage forms comprise water soluble and swellable polymers such as gellan gum, hydroxypropylmethyl cellulose, carboxymethyl cellulose sodium salt, xanthan gum, guar gum, or blends thereof (Col. 5, Lns. 55-67; Col. 10, Lns. 5-15). According to Wong said polymers may constitute from 10 to 50 % of the matrix (Col. 6, Lns. 45-50) to provide the desired retention time in the stomach and the desired release profile of active agent (Col. 11, Lns. 16-25). The active compounds incorporated in such dosage form include metformin, orlistat, levodopa (Col. 18, Lns. 31-54), ciprofloxacin or clarithromycin (Col. 19, Ln. 27 and Col. 20, Ln. 15) and alike.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize the blends of hydrophilic and swellable polymers taught by Wong in pharmaceutical articles taught by Skinner, because Wong teaches that such compositions are adapted for retention in the stomach and are useful for prolonged delivery of an active formulation to a fluid environment providing a distinct drug release profiles.

Claims 1, 3-5, 7-8, 10 and 12-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Skinner, U.S. 6,210,710 (hereinafter referred to as Skinner) and Baichwal et. al., U.S. 2003/0129230 (hereinafter referred to as Baichwal).

The teachings by Skinner are outlined above. Skinner does not disclose wherein gellan gum constitutes from about 20 to about 50 wt % of the matrix (Claim 1). Skinner is silent regarding the drug has preferred absorption in the stomach (Claim 6). Skinner does not teach upon wetting the dosage form, a gel is produced for more than 5 hours (Claim 18); more than 24 hours (Claim 19); or more than 1 week in gastric fluid simulation (Claim 20).

Baichwal teaches an active agent dosage form which is adapted for retention in the stomach and useful for the prolonged delivery of an active agent formulation to a fluid environment of use (Abstract). Baichwal also teaches said dosage forms comprise hydrophilic compounds (Para. 0007) such as gellan gum, hydroxypropylmethyl cellulose, carboxymethyl cellulose sodium salt, xanthan gum, guar gum, and/or mixture thereof (Para. 0018 and Claims 12 and 51). According to

Baichwal said polymers may constitute from 20 to 80 % of the matrix (Para. 0017) to provide the desired retention time and/or release profile of active agent (Para. 0025, 0046). Baichwal also teaches wherein said compositions provide a gel matrix in the gastrointestinal fluids in the stomach (Para. 0019, 0042).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize the hydrophilic compositions taught by Baichwal in pharmaceutical articles taught by Skinner, because Baichwal teaches that such compositions are adopted for retention in the stomach and are useful for prolonged delivery of an active formulation to a fluid environment providing a distinct drug release profiles.

Response to Argument

(1) Applicant's arguments filed 04/14/2011 with respect to the 35 U.S.C. 103(a) rejection of Claims 1-3, 8, 10 and 12 over Skinner (U.S. 6,210,710) been fully considered and are persuasive. The rejection has been withdrawn;

(2) Applicant's arguments filed 04/14/2011 with respect to the 35 U.S.C. 103(a) rejection of Claims 1-3, 8, 10 and 12 over Baichwal (U.S. 5,958,456) in view of Skinner (U.S. 6,210,710) been fully considered and are persuasive. The rejection has been withdrawn;

(3) Applicant's arguments filed 04/14/2011 with respect to the 35 U.S.C. 103(a) rejection of Claims 1, 3, 5, 8, 10 and 12 over Illum (U.S. 5,935,604) been fully considered and are persuasive. The rejection has been withdrawn.

However, upon further consideration, a new ground(s) of rejection is made in view of Skinner, U.S. 6,210,710 and Wong et. al., US 6,548,983 and in view of Skinner, U.S. 6,210,710 and Baichwal et. al., U.S. 2003/0129230.

Conclusion

No claim is allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga V. Tcherkasskaya, Ph.D. whose telephone number is (571)270-3672. The examiner can normally be reached on 8am - 5 pm, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571)272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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